

Serial No. 10/602,215
PC 21501B

REMARKS

I. Status of the Application

This paper responds to a Non-Final Office Action mailed on September 13, 2004, which rejected claims 1-15. The application was originally filed with claims 1-15. This paper amends claims 1-3, 5-10, and 13-15 and adds no new claims. Therefore, claims 1-15 are currently under consideration in the present application. Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks. By action taken here, Applicant does not intend to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Amendment of Claims 1-3, 5-10, and 13-15

Applicant has amended all of the independent claims so that they now recite that the one or more polyhydric alcohols comprise at least 25% weight/volume of the composition (claim 14) or about 25% to about 75% weight/volume of the composition (claims 1, 6, 9, and 10). Applicant has amended claims 2 and 8 so that they are consistent with claims 1 and 6, respectively; has amended claim 15 so that it recites a method of treatment; and has amended claims 1-3, 5-10, 13, and 14 to correct grammar informalities and to improve readability. The specification and claims, as filed, fully support the changes to the claims, and therefore Applicant submits that the present amendment introduces no new matter.

III. Objection to Claim 15 Under 37 CFR § 1.75

The Office Action objected to claim 15 under 37 CFR § 1.75 as allegedly "being a substantial duplicate of claims 1 and 13." As suggested by the Examiner, Applicant has amended claim 15 to recite a method of use, thereby obviating this objection. Applicant respectfully requests withdrawal of the objection.

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IV. Rejection of Claims 1-5 and 12-15 Under 35 U.S.C. § 112, ¶ 2

The present Office Action rejected claims 1-5 and 12-15 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. According to the Office Action, claim 1 “does not recite a GABA analog in the body of the claim” and the “first time that an abbreviation appears in a claim it should be in parentheses and be preceded by the term for which it is an abbreviation.” The Office Action also contended that the ingredients in claim 5 lack antecedent basis and that the phrase “characterized by” in claim 14 is colloquial and unclear. Applicant has amended claim 1 so that “GABA analog” appears in the body of the claim and has added the phrase “gamma-aminobutyric acid (GABA).” Applicant has also amended claim 5 to provide antecedent basis for the “preservative” and “flavor” and has deleted the phrase “characterized by” in claim 14, thereby obviating the rejections. Applicant respectfully requests withdrawal of these rejections.

V. Rejection of claims 1-15 Under 35 U.S.C. § 103

The Office Action rejected claims 1-15 under 35 U.S.C. § 103 as being unpatentable over WO 99/58573. According to the Office Action, “WO 99/59573 (page 50, lines 7-21, pages 58-61, Examples 2 and 3) discloses a liquid composition of a GABA analog comprising a polyhydric alcohol containing 2-6 carbon atoms. It discloses the use of a sweetening agent and a flavoring agent on page 50. The examples further disclose formation of the lactam degradation product is limited by the addition of the polyhydric alcohol.” Applicant respectfully submits that claims 1-15 are patentable over WO 99/59573 and all other references cited in the Office Action.

As noted above, Applicant has amended all of the independent claims so that they now recite that the one or more polyhydric alcohols comprise at least 25% weight/volume of the composition (claim 14) or about 25% to about 75% weight/volume of the composition (claims 1, 6, 9, and 10). Neither WO 99/58573 nor any of the other references cited in the Office Action teaches or suggests these limitations, and therefore, Applicant submits the references cannot anticipate claims 1-15.

Furthermore, Applicant submits that WO 99/58573 cannot render the claims obvious. As noted in the application, Applicant has discovered that a GABA analog can

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be formulated in a stable liquid pharmaceutical composition having low levels of a GABA analog lactam when the pH of the composition is about 5.5 to about 7.0 and when the composition includes one or more polyhydric alcohols. See Specification, page 4, lines 4-7, and page 9, lines 7-9. Nothing in WO 99/58573 teaches or suggests that this pH range and the addition of one or more polyhydric alcohols in the claimed amounts would result in a stable liquid pharmaceutical composition containing a GABA analog.

Moreover, WO 99/59573 teaches away from the use of a polyhydric alcohol in pharmaceutical compositions containing a GABA analog. Contrary to the assertion in the Office Action, WO 99/59573 does not "disclose formation of the lactam degradation product is limited by the addition of the polyhydric alcohol." Instead, Example 2 in WO 99/59573 shows that the addition of a polyhydric alcohol (xylitol, sample e) to an aqueous gabapentin solution increases lactam formation (compare sample d and sample e in Table 4). The addition of glycine (sample f) to an aqueous solution of gabapentin and xylitol appears to decrease lactam formation (compare sample f with samples d and e in Table 4). Thus, WO 99/59573 states that Table 4 "shows that gabapentin in its aqueous solution could be similarly prevented from the degradation with lapse of time (the lactam formation) by the addition of glycine even in the presence of xylitol," i.e., despite the presence of xylitol (emphasis added). Applicant, therefore, respectfully requests withdrawal of the rejection.

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VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant submits that no fees are due with respect to the filing of this amendment. However, if any fees are required in connection with this amendment, please charge deposit account number 23-0455.

Respectfully submitted,

Date: December 13, 2004



Matthew J. Russo, Reg. No. 41,282
Warner-Lambert Company LLC
2800 Plymouth Road
Ann Arbor, MI 48105
Tel: (734) 622-1747
Fax: (734) 622-2928
Customer No. 28880

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